Remarks

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Claim 1 has been amended to more clearly define the oral suspension claimed by Applicant. Support for the amendment to Claim 1 can be found — at least — at page 2 and in Examples 3 & 4 of Applicant's disclosure.

Claims 16 and 17 are newly added. Support for the additional claims can be found — at least — at Example 2 of Applicant's disclosure. No new matter has been added.

Claims 1, 8, 9, 13, and 16 and 17 are presently pending in the Application, with Claims 1, and 16 being the independent claims.

I. Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 5, 7-9, 13 and 15 stand rejected under 35 U.S.C. § 112, Second Paragraph as being indefinite.

In light of the amendments to Applicant's claims, specifically regarding the recitations of "mixture" and "partitioning", the rejection is moot. As such, Applicant respectfully requests that the rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

II. Rejection of Claims under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1, 5, 7 – 9, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over De Bruijn (WO0010526) in view of Patel (US 20030180352) and in further view of the combination of Achong (US 20040162273), Belcheff (US 20010031283, Naicker (US 7060672) and Allen et al, *Am. J. Health Syst. Pharm.* (1995). Applicant respectfully traverses the rejection.

In making the Section 103(a) rejection, the Examiner cites DeBruijn as teaching a composition for administering an acid-sensitive active ingredient that is poorly soluble. The Examiner also cites Patel as teaching solid carriers to improve the delivery of active ingredients in pharmaceutical ingredients by masking the taste. The Examiner states that

one skilled in the art would be motivated to combine DeBruijn and Patel to mask the unpleasant taste for the drugs disclosed.

The Examiner also turns to Achong for teaching a powder pharmaceutical composition that can be formulated to contain aesthetically pleasing flavor and sweetener ingredients when dissolved in beverages, such as cold water and apple juice. Belcheff is then cited for teaching apple juice as a preservative with pursiane. Naicker is cited for teaching an antibiotic dissolved in apple juice; the apple juice possibly responsible for superior drug bioavailability. The Examiner cites Allen for teaching the stability of ramipril in water, apple juice and apple sauce at room temperature and 4°C.

The Examiner states that one skilled in the art would be motivated to combine the tablet of tegaserod disclosed by DeBruijn or Patel to apple juice as disclosed by Achong, Belcheff, Naicker and Allen because the references disclose that apple juice has an aesthetically pleasing flavor, a preservative property, a taste masking effect, a bioavailability providing property, properties for reducing adverse effects and a stabilizing agent.

Applicant respectfully disagrees with the Examiner's conclusion and submits that Applicant's present claims are not obvious in light of the references cited. Applicant submits that neither DeBruijn nor Patel teach, suggest, or provide motivation to use a homogenous oral suspension comprising apple juice and tegaserod to provide administration of a partitioned dose of tegaserod. Neither DeBruijn nor Patel teach a known and fixed amount of active ingredient as a component of a homogenous suspension, wherein the dosage of the active ingredient is capable of being partitioned, as expressly recited by Applicant's claims. DeBruijn does not teach a homogenous oral suspension and is solely dedicated to tablet forms of tegaserod. Nor does Patel teach suspensions; rather Patel is directed at solid form compositions, such as chewable tablets, film, etc.

In determining the scope and content of the prior art, the scope of the claimed invention must be clearly determined by giving the claims the "broadest reasonable interpretation consistent with the specification." See Phillips v. AWH Corp., 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § 2111. The subject matter of

the claims must be considered as a whole; "all words in a claim must be considered". *In re Wilson*, 424 F.2d 1382, 1385; 165 USPQ 494, 496 (CCPA 1970).

Applicant's claims — given their broadest reasonable interpretation and consideration of all words in the claims — encompass specific elements that are missing from the prior art.

Applicant's homogenous oral suspension is an alternative method of tegaserod administration which is especially suitable for partitioning a dosage of tegaserod and for a patient's use at home. At the time of the invention, tegaserod was not available as an oral solution, or in dosages other than 6 or 2 mg tablets. Moreover, tablets of tegaserod do not have a partition line. As a result, there was no procedure or method for administering tegaserod in a particular dosage other than 2 mg or 6 mg.

Applicant respectfully asserts that the combination of Achong, Belcheff, Naicker and Allen fails to cure the defects of the DeBruijn and Patel combination. Also, Applicant respectfully asserts that Naicker is not a valid reference for prior art purposes because the patent date of June 13, 2006 is two years after the priority date of Applicant's present Application, which is March 30, 2004. As such, Applicant respectfully requests that the Examiner disqualify Naicker as a reference in the present Action.

Applicant has discovered that apple juice has an unexpected advantage and superior results, specifically a superior dissolution profile, when compared to other masking agents discussed in the prior art, such as orange juice and apple sauce. See Example 3 of Applicant's specification where Applicant found that dissolution profile of the tegaserod with orange juice is less favorable, i.e. around 58% dissolution after 60 minutes.

Applicant has discovered that the dissolution of crushed tablets of tegaserod in apple juice was complete in five minutes and that the tegaserod was stable in apple juice for up to one hour at room temperature and up to three days when stored properly, providing a superior dissolution profile when compared to orange juice. (See Example 3 of Applicant's specification; See Carrier, Page 1140)

Applicant's homogenous oral suspension — as expressly claimed — also overcomes the problem of administering tegaserod in a liquid formulation, complete with acceptable criteria for dosage, dissolution, stability and homogeneity. Current dosage

formulations for tegaserod do not allow administration of tegaserod in a particular dosage other than 6 mg or 2 mg tablets. The oral suspension of Applicant's claims, however, is capable of providing a partitioned dose of tegaserod via administration of the suspension over the course of a day, or even over the course of days.

Achong, Belcheff nor Allen teach or suggest using the superior dissolution and partitioning properties of a homogenous suspension comprising tegaserod in apple juice, for the partitioning of the dose of tegaserod, as expressly recited by Applicant's claims. Most significantly, the references fail to recognize that apple juice is preferable to a host of other aesthetically pleasing flavors and sweetener ingredients for specific and non-obvious reasons, such as dosage homogenization and partitioning. For instance, while the Examiner cites Allen for teaching stability of ramipril over a time course of up to 48 hours when dissolved in apple juice, water or apple sauce, no difference between the three were shown. Apple juice, water and apple sauce all provided a stable dissolution environment for ramipril, thus there is no teaching that apple juice exhibited superior stabilization properties over other alternatives, such as water. Ramipril stability may indeed have nothing to do with the liquid in which it is dissolved, but rather, stability may be a factor inherent in the chemical make-up of the compound itself.

Thus, in view of the foregoing remarks, the cited references singularly or in combination, fail to teach, or suggest each and every claim limitation of Applicant's claims to support the Examiner's rejection under 35 U.S.C. § 103(a).

In view of the above, Applicant respectfully requests the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §103.

III. Conclusion

In view of the foregoing, Claims 1, 8, 9, 13, 16 and 17 are in condition for allowance, and Applicant earnestly solicits a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration to this Amendment and Reply is respectfully requested.

Respectfully submitted,
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